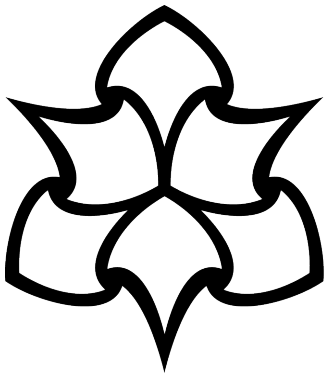

Title:

Is there an association between back pain and stress incontinence in adults with cystic fibrosis? A retrospective cross-sectional study.

Running title:

Back pain and stress incontinence in adult CF.

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Keywords: Cystic Fibrosis; back pain; stress urinary incontinence; lung function; cross sectional study

Abstract.

Background: Back pain and stress urinary incontinence (SUI) are common in adults with cystic fibrosis (CF). This study aimed to establish whether there is an association between back pain, lung function and stress urinary incontinence and its relative risk.

Method: This was a cross-sectional, retrospective analysis of the Manchester Musculoskeletal Screening Tool (MMST) data. It includes pain, (Short Form McGill Pain Questionnaire (SF-MPQ and VAS)) and International Consultation on Incontinence Short Form (ICIQ-UI-SF) measures. Associations were tested using Spearman's rank correlation coefficient. Relative risk of developing symptoms was calculated ($p \geq 0.05$).

Results: ICIQ-UI-SF was associated with back pain (SF-MPQ) (Rho = 0.32, $p < 0.001$) and pain (VAS) (Rho = 0.23, $p < 0.01$). RR of developing SUI with back pain was 2; RR of developing back pain with SUI was 1.3.

Conclusions: An association is indicated between back pain, pain and SUI in adults with CF. This information is important when developing management strategies in the CF population.

Background.

Despite improvements in management, CF remains a progressive disease. Adulthood survival brings new complications including musculoskeletal abnormalities. These are related to the conflicting demands of respiration and posture in conjunction with reduced bone mineral density (BMD) and muscle mass [1]. Fracture rates in patients with CF have been reported as twice as high as their peers by age 16, 62% of adults had excessive kyphosis and 94% reported back pain [2].

Puberty is a significant period as 25% of bone density is amassed when peak height is reached, children with CF only acquired half as much bone as healthy children [3]. Reduced bone mineral density in adults with CF is thought to be a combination of sub-optimal maturity of bone in puberty and rapid bone loss as an adult. Adults with CF have significantly reduced quadriceps strength and muscle mass compared to matched controls; this may be due to reduced activity levels and decreased BMD as opposed to reduced force generating capacity of the muscle [4].

Back pain and postural deformities are common in CF and appear to be associated with deteriorating lung function [5]. Using the CF QOL questionnaire, poor physical functioning and the presence of pain were the strongest predictors of reduced survival in CF [6]. Pain is a frequent and devastating problem in adults with CF with back pain being the most common complaint [7].

There is an interaction between muscles of postural stability and respiration and most muscles have dual roles and act to support both systems [8]. Control of increased intra-abdominal pressure is performed automatically as a feed-forward loop via the recruitment of transverse abdominis, the diaphragm and the pelvic floor. Electromyographic (EMG) recordings of the diaphragm and other trunk muscles have shown that co-ordination of tonic and phasic activities in the diaphragm and transverse abdominis is reduced or absent after only 60s of hypocapnea [9]. Therefore, when the chemical drive to breathe is increased the muscles forego their postural role. Therefore, back pain is prevalent in adult CF where there is an imbalance between respiratory and postural demand on a spine disadvantaged by insufficient BMD and reduced muscle mass.

Stress urinary incontinence (SUI) is a secondary complication of CF involving the external support system. 70% of women with CF over 35 years of age in Manchester reported SUI [10], compared to 35% of the English and Welsh population [11]. When coughing, intra-abdominal pressure increases due to contraction of the abdominal muscles and diaphragm imposing downwards pressure on the pelvic floor muscles; the valsalva manoeuvre. Evidence suggests that adolescent females with CF and high severity of cough are less able to reduce the displacement of the pelvic floor when coughing [12]. If the pelvic floor is unable to generate adequate, coordinated counter pressure or lacks endurance, SUI results. Frequent bouts of intense coughing in CF, especially during an exacerbation, coupled with lack of co-ordination between respiration and posture and potential reduced strength and mass of the pelvic floor mean that SUI is a significant problem in this population compared to asthmatics and normal controls [13].

There is a growing body of evidence demonstrating links between SUI and back pain [14-16]. In a study of 38,050 healthy Australian women [14], self-report data was used to establish associations between back pain, pelvic floor weakness and disorders of respiration, while considering confounding factors of BMI and physical activity. In contrast to BMI and physical activity, disorders of continence and respiration were related to back pain across all ages. A cross-sectional study of 2,341 women from the Kentucky concluded that women with chronic low back pain have increased chance of developing SUI, indicating the importance of all muscles of the trunk, including the pelvic floor to function in co-ordination with one another [15], and a study of 220 women in Stockholm found 78% of women with recurrent low back pain also reported experiencing SUI [16].

Back pain and SUI are two of the most common disorders of the external support system found in CF. No studies have specifically targeted a CF population to investigate links between the two conditions. This study aims to add to the evidence base and determine, in an adult CF population, whether there is an association between back pain, lung function with SUI and its relative risk.

Method

This was a cross-sectional retrospective evaluation of patient records [17]. In 2012, there were 379 active patients registered at the Manchester Adult Cystic Fibrosis Centre. Annually, all patients are invited to attend a multi-disciplinary review. All physiotherapists undertaking annual review in 2012-13 were invited to administer the Manchester Musculoskeletal Screening Tool (MMST).

Permission for analysis and publication of patient data was obtained from the data control department, University Hospital South Manchester. Ethical approval was obtained from Manchester Metropolitan University. This study is reported according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement [18].

Outcome measures

All outcome measures were collected on admission to the centre and then at annual review. All outcomes except FEV_1 were self-reported by a specialist CF physiotherapist trained in administering the outcome measures. FEV_1 was measured using Vitalograph wedge-bellows spirometers.

The **MMST** is a valid assessment of pain and urinary incontinence with an additional brief assessment of suboptimal spinal posture and movement in adults with CF [19]. It was developed in response to, and has been used for identification of, the prevalence of musculoskeletal disorders in adults with CF [20]. It consists of the Short-form McGill Pain Questionnaire (SF-MPQ) [21,22], the Visual

Analogue Scale (VAS) [22] and the International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form (ICIQ-UI-SF) [23].

The **SF-MPQ** [21], and **VAS** [22] were included to identify the presence and extent of pain (Permission granted by the Mapi Research Trust). The measurement of pain is challenging due to its subjective and complex nature; in order to overcome this, it is suggested that the VAS, as a one-dimensional measure of pain intensity, and the SF-MPQ as a multidimensional measure of pain are used together [22]. The SF-MPQ consists of two parts: the first is 15 descriptors (11 sensory; 4 affective), to help describe pain during the last 7 days, rated on a Likert Scale: 0 = none, 1 = mild, 2 = moderate or 3 = severe. The second is a Present Pain Intensity score: 0 (no pain) to 5 (excruciating). Total **SF-MPQ** pain scores are derived from the sum of the pain over the last 7 days and the Present Pain Intensity score. The minimum score is zero and the maximum score is 50 [21]. Finally, a VAS was included, using a 10 cm line bounded with the descriptors“no pain” at one end and “worst possible pain” at the other; the minimum score was zero and the maximum score was 100.

The **ICIQ-UI-SF** [23] is a valid and reliable measure of stress urinary incontinence [24]. It has good content and construct validity, demonstrating a clear differentiation between sex and perceived causes of incontinence [23]. It provides a consistent and unified approach to the measurement of incontinence and its impact on quality of life across the general population [23]. The questionnaire consists of three questions summed into a single total score. The minimum score is 0 and the maximum score is 21.

The **percentage of predicted FEV_1** ($\%FEV_1$), is the patient percentage of predicted FEV_1 divided by the average population percentage of predicted FEV_1 for any person of similar age, sex and body composition. It is commonly used to measure lung function in CF [25]. $\%FEV_1$ was calculated using the Pulmonary Function Reference Normal Predicted Values Calculator from The Centre for Disease Control and Prevention (http://www.cdc.gov/niosh/topics/spirometry/RefCalculator.html).

Data analysis

Data were analysed using IBM SPSS Statistics version 21. SF-MPQ and ICIQ-UI-SF data were ordinal. $\%FEV_1$ and VAS were scale data. Normality was determined using the Shapiro-Wilk test. Relative risk (RR) was calculated as the ratio of the risk of developing SUI with back pain to the risk of developing SUI without back pain. The 95% confidence interval was included for the RR; a value of 1 is indicative that the estimated risks in both groups are the same. VAS and $\%FEV_1$ data were not normally distributed, therefore the Spearman’s Rank Correlation Coefficient was used to determine associations between back pain and SUI. Bootstrapping was used to determine 95% confidence intervals for the Spearman’s Rank Correlation Coefficient. Significance was set at $p< 0.05$. Out of 1260

questions, 5 items (0.004%) were missing, n=2 FEV_1 values, therefore n=2 $\%FEV_1$ values could not be predicted and n=1 age, rendering this only a minor nuisance [26].

Results

In 2012-13, 379 active patients were registered at the Manchester Adult Cystic Fibrosis Centre. N=126 (33%) patients completed the MMST and had a similar median age [median age = 26] to those who did not [median age = 28 years]. N=126 MMST screening tools were included in the study. Demographics for the participants can be found in Table 1. Although, not the focus of the study, results for males, females, and all patients are presented. Outcomes were similar for both groups except for VAS and SF-MPQ. Overall, females reported less pain with n=33 scoring zero [median = 0 (IQR = 34) range 0 - 111] on the VAS, compared to n = 18 males [median = 34 (IQR = 51) range 0 - 112]. There is a similar picture for the SF-MPQ; overall, females reported less pain with n = 35 scoring zero [median = 0 (IQR = 7), range 0 - 27] on the SF-MPQ, compared to n = 14 males [median = 6 (IQR = 12) range 0 - 36]. Although 33% of patients from the Manchester Adult Cystic Fibrosis Centre were included in the study, their lung function was similar to that of epidemiological data [27]. In the current study, at a median of 26 years old, $\%FEV_1$ was 51%, compared to epidemiological data (n = 20,644) a median of 26 years old, $\%FEV_1$ was approximately 55% [27].

Table 1. Demographics of population

	Males median (IQR) min-max	Females median (IQR) min-max	Total median (IQR) min-max
Sex	N = 64 (51%)	N = 62 (49%)	N = 126 (100%)
Age (years)	31 (19) 18 - 53	24 (10) 18 - 55	26 (14) 18 - 55
Height (cm)	166 (13) 144 - 186	167 (14) 147 - 190	167 (14) 144 - 190
FEV_1 (L)	2.2 (1.6) 0.5 - 5.45	1.3 (1.1) 0.4 - 4.6	1.8 (1.3) 0.4 - 5.5
% FEV_1	48 (34) 12 - 110	52 (41) 13 - 136	51 (37) 12 - 136
ICIQ-UI-SF	0 (5) 0 - 14	0 (0) 0 - 21	0 (4) 0 - 21
VAS	34 (51) 0 - 112	0 (34) 0 - 111	20 (51) 0 - 112

SF-MPQ	6 (12) 0 - 36	0 (7) 0 - 27	3 (10) 0 - 36

FEV_1 = Forced expiratory volume over $1s^{-1}$ [litres]

$\%FEV_1$ = percentage of predicted FEV1 [normal = 80 - 120% of average]

ICIQ-UI-SF = International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form [scale 0 - 21]

VAS = Visual Analogue Score [scale 0 - 100]

SF-MPQ = Short-form McGill Pain Questionnaire [scale 0 - 50]

N = 87 patients out of n = 126 (69%) reported the presence of back pain. N = 43 patients out of n = 126 (34%) reported the presence of SUI. N = 35 (28%) of the total cohort reported both back pain and SUI (Table 2). The RR of experiencing SUI when you have back pain was twice that of when not having back pain (Table 2). Conversely, the RR of experiencing back pain when you have SUI was 1.3 times that of when not having SUI. Both were deemed statistically significant (p = <0.05).

Table 2. The relative risk of developing SUI with or without the presence of back pain.

		Presence of stress urinary incontinence (ICIQ-UI-SF) N = (%)			**RR (95% CI) p =**
		Yes	No	Total	
Presence of back pain (SF-MPQ) N= (%)	Yes	35 (40)	52 (60)	87 (100)	2.0 (1.0 to 3.8) 0.04
	No	8 (21)	31 (79)	39 (100)	
	Total	43 (34)	83 (66)	126 (100)	
RR (95% CI) p =		1.3 (1.0 to 1.6) 0.02			

ICIQ-UI-SF = International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form [scale 0 - 21]

SF-MPQ = Short-form McGill Pain Questionnaire [scale 0 - 50]

We found higher pain scores were associated with a higher SUI score. A weak to moderate positive association was found between SF-MPQ and ICIQ-UI-SF and a weak positive association between the VAS and ICIQ-UI-SF (Table 3, Figs 1 and 2). No significant correlations were found between $\%FEV_1$ and SF-MPQ (*Rho* = 0.11, p = 0.22, 95%CI - 0.06 to 0.29), VAS (*Rho* = 0.12, p = 0.19, 95%CI - 0.05 to 0.29), or ICIQ-UI-SF (*Rho* = 0.04, p = 0.22, 95%CI - 0.06 to 0.29).

Table 3. Spearman's Rank Correlation Coefficient for pain (SF-MPQ, VAS), $\%FEV_1$ and SUI (ICIQ-UI-SF).

N = 126	**ICIQ-UI-SF**		
	Correlation coefficient	p =	95% confidence interval
SF-MPQ	0.32	< 0.001	0.15 to 0.47
VAS	0.23	< 0.01	0.09 to 0.43
$\%FEV_1$	- 0.096	0.28	-0.25 to 0.07

ICIQ-UI-SF = International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form.

VAS = Visual Analogue Score.

SF-MPQ = Short-form McGill Pain Questionnaire.

$\%FEV_1$ = percentage of predicted FEV1.

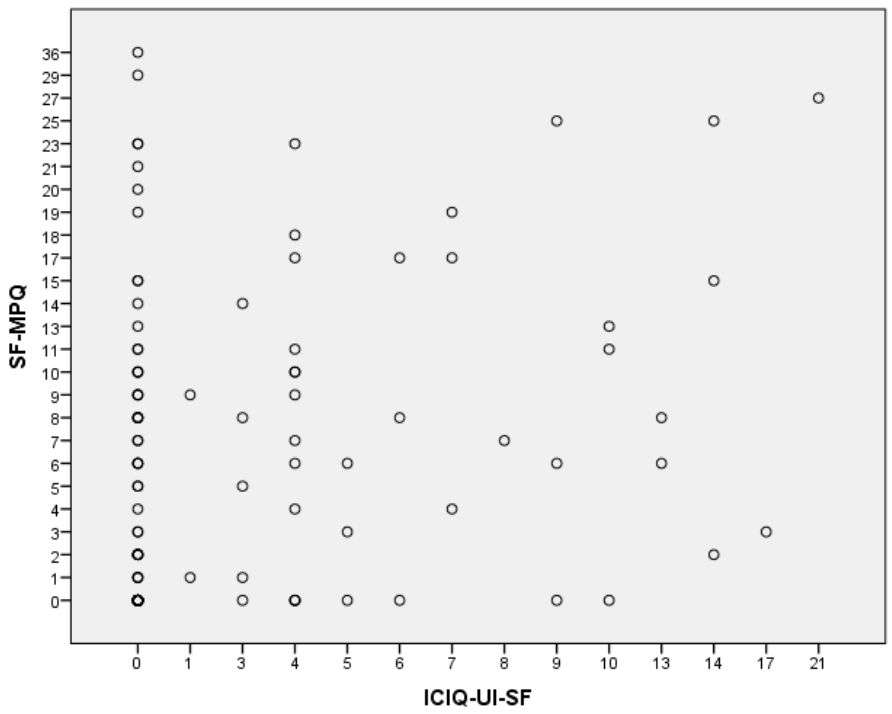

Figure 1. Scatter plot of SF-MPQ and ICIQ-UI-SF scores for the Manchester Adult Cystic Fibrosis Centre population, 2012-3.

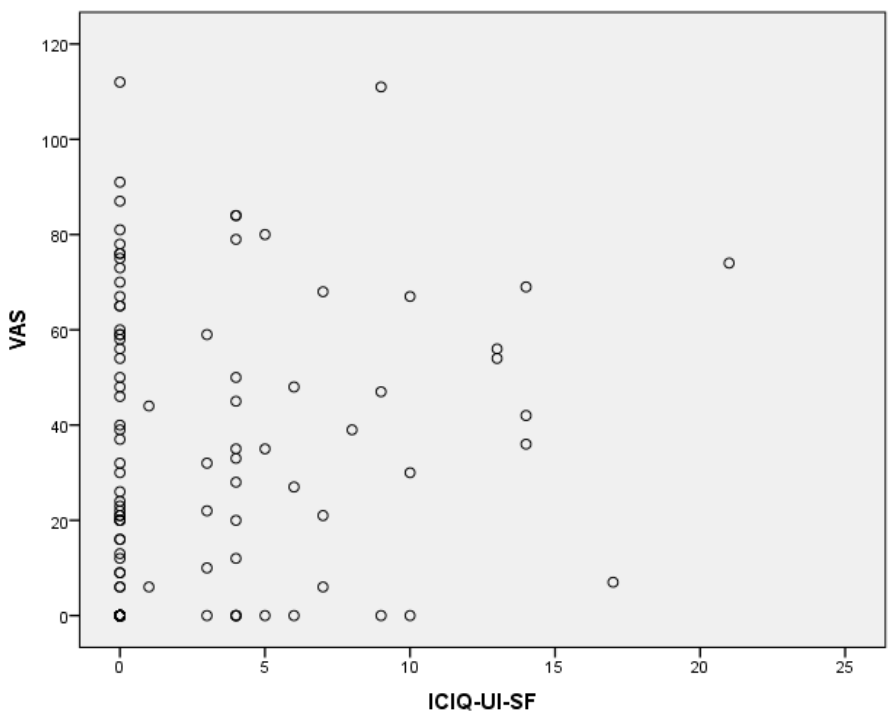

Figure 2. Scatter plot of VAS and ICIQ-UI-SF scores for the Manchester Adult Cystic Fibrosis Centre population, 2012-3.

Discussion

The aim of this study was to determine whether there is an association between back pain, lung function and SUI and the relative risk of having SUI with back pain.

We found at the Manchester Adult Cystic Fibrosis Centre, that there is a relationship between back pain and SUI and patients with CF and low back pain are twice more likely to experience SUI than those without. This accompanies the knowledge that patients with

CF are more likely to suffer with low back pain and SUI than as the general population. The relative risk of developing low back pain in the presence of SUI is less convincing.

The increased prevalence of SUI in the presence of low back pain could be the result of the clinical manifestations of pelvic floor dysfunction. The pelvic floor provides a significant contribution to spinal stability as well as maintenance of continence [29]. Transverse abdominal ultrasound has been used to determine pelvic floor function in women with back pain; it has shown that those with back pain have significantly lower pelvic floor muscle function than those without [29]. In the presence of pain, the pelvic floor along with the diaphragm and transversus abdominis can lose its ability to co-contract as part of a feed-forward loop in the anticipation of movement or stress on the spine. In the presence of respiratory dysfunction, these muscles forgo their postural role in response to the brain's drive to breath and act as accessory muscles to respiration. This alteration in muscle function can leave the spine vulnerable to injury.

It is a surprising finding that the severity of lung disease (measured by FEV_1) does not have a significant relationship to SUI or pain in this study population. The methods by which patients clear secretions, exercise and cough have potential to exert very large forces on the pelvic floor and abdominal muscles regardless of the severity of lung disease. Patients with CF commonly use a prolonged and high severity cough to clear secretions from their chest [30]. Displacement of the pelvic floor during this cough is poorly controlled [12], therefore during a chest exacerbation, it is likely that the pelvic floor is unable to maintain intra-abdominal pressure thereby leaving the spine more vulnerable to injury and increasing the likelihood of SUI.

Conversely, the ability to cough might reflect good control of the pelvic floor and abdominal muscles, therefore preventing the likelihood of back pain and SUI. Evidence shows pelvic floor muscle activity significantly increases during abdominal contractions [28]. It is suggested that pelvic floor muscle activity occurs in advance of both involuntary (e.g. cough) and voluntary contraction of the abdominal muscles and that contraction of the abdominal muscles may provide an efficient mechanism with which to initiate and co-ordinate contraction of the pelvic floor muscles [28]. Training the pelvic floor muscles could provide an efficient mechanism to contribute to spinal stability by improving the increase and control of intra-abdominal pressure by co-ordinating with abdominal muscle contraction.

The strengths of this study include the completeness of the data set; only five out of 1260 items were missing, limiting bias [17]. Comprehensive and relevant outcomes were included; the MMST includes valid and reliable pain and SUI questionnaires specific to CF and the aims of this study. Another strength was that the participants included were those that attended the annual review. Because the same clinicians carry out the annual review, this limited the bias involved in the care and data collection [17]. The annual review consists of appointments with a combination of health care professionals, for example, respiratory doctor, physiotherapist, social worker, nurse, psychologist, diabetic doctor, rheumatologist, and has investigations such as blood tests, X-rays and spirometry

taken.

Limitations of this study include the lack of data concerning patients who did not attend the annual review or complete the MMST. It is not known whether the participants reflect all the 379 active patients registered at the Manchester Adult Cystic Fibrosis centre, however, the lung function (%FEV_1) of those included in the study is similar to epidemiological data [27]. Reasons for not attending the annual review include adequate self-management, poor engagement with the Centre, difficulties related to preventing cross infection, difficulties transitioning from paediatric to adult care, and reasons for not completing the MMST include time constraints, clinic capacity and other interventions taking priority at annual review due to the complex needs of individual patients. The limitations of retrospective studies are well documented [17], and BMI, BMD, frequency or intensity of cough and CF quality of life measures would be useful outcomes to determine causation rather than associations, as in the current study, in order to improve the management of CF. Any association between back pain and an increased prevalence of UI could be better investigated via a longitudinal, prospective study initiated in a paediatric centre. It would be useful to collect data prior to the onset of pain and UI and follow patients with CF through transition into an adult centre.

The association between force and length of cough, and pelvic floor and abdominal muscle strength, in co-ordination with the presence of SUI and low back pain might provide more information about why this association exists. A study examining the effects of pelvic floor functional retraining on back pain and SUI in this population would provide useful insight to help inform treatment strategies for both conditions in a patient group already laden with a huge burden of care.

In conclusion, this study indicates that there might be an association between SUI and low back pain in the Manchester adult cystic fibrosis population as indicated by the MMST screening tool data. The relative risk of patients with CF experiencing SUI with back pain is twice of that without back pain. Lung function is not associated with back pain or SIU. Despite this, these results are an indication of the intricate relationships that exist between the respiratory, continence and musculoskeletal systems and must be addressed by the multi-disciplinary team when planning the details of each individualized, specific and holistic package of care.

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